REMARKS

Prior to this amendment, claims 36-43 and 51-57 were pending in this application, with claims 51-57 having been withdrawn from consideration. To place this application in condition for allowance, withdrawn claims 51-57 are now canceled. Upon entry of these amendments, claims 36-43 will be pending in this application.

ELECTION OF CLAIMS

In response to the restriction requirement made by telephone on January 26, 2007, Applicant elects claims 36-43 for examination. Applicant reserves the right to prosecute non-elected claims in a divisional application.

REJECTIONS UNDER § 103

Claims 36-43 were rejected under § 103(a) as being unpatentable over *Zadno-Azizi* et al. (WO 97/04895) in view of *Yoon* (U.S. Patent No. 5,908,429). The Office Action suggests that the shape memory actuator of *Zadno-Azizi* could be modified to have the finger portions taught by *Yoon*. Applicant respectfully submits that this combination of *Zadno-Azizi* with *Yoon* is not suggested by the references and could only be made through impermissible hindsight using Applicant's invention as a guide.

A. The Different Medical Applications of *Yoon* and *Zadno-Azizi*

Yoon describes an endoscopic tissue ligation instrument (see col. 5, lns. 36-41). The ligation instrument is used to grasp anatomical tissue (e.g., fibroids, polyps, gall bladders, tumors) place a ligature loop around the tissue, and contract the ligature loop to tie-off the tissue so that it can be severed (see Abstract and col. 13, lns. 43-46).

Zadno-Azizi describes a composite structure formed of a shape memory alloy (see Abstract). Specific applications for the composite structure include radio antennas, robotic devices, mechanical devices, valve actuators, flow controllers, and thermal relays (see p. 12, lns. 23-26; and p. 13, ln. 27 – p. 14, ln. 4). With respect to medical applications, *Zadno-Azizi* provides only a single limited example – guidewires for use in angioplasty procedures (see p. 12,

lns. 19-22). This single example would not lead a person of ordinary skill in the art to consider the endoscopic ligator of *Yoon*, which is an entirely different type of medical device, for an entirely different medical procedure, within a different medical specialty.

Modern medicine has access to an enormous array of medical devices for use in an large and steadily growing body of medical procedures. Any person having expertise in medical devices would be challenged to grasp the full breadth of modern medical technology. In fact, much of modern medicine is practiced within highly specialized branches of medicine such as cardiology, surgery, orthopedics, gynecology, or neurology. Understandably then, medical devices are generally conceived, designed, developed, clinically tested, and marketed for use with a particular application in mind.

In view of this reality, it is no surprise that *Zadno-Azizi* provides only a single example that focuses on one particular type of device (i.e., a guidewire) for use in one particular type of medical procedure (i.e., angioplasty) within one particular medical specialty (i.e., cardiology). While this single limited example may speak to a person working in the field of intravascular cardiac devices (which, by itself, is a large and rapidly growing specialty), it fails to address a person working in any other field of medical devices (such as endoscopic surgery). Having not provided an example of any other device, nor of any other medical procedure, nor of any other medical specialty, a person of ordinary skill in this highly specialized art would not consider the single limited example provided by *Zadno-Azizi* to be suggestive of the endoscopic ligator in *Yoon*.

Although the example of a guidewire device may be suggestive of an intravascular cardiac catheter device (which is deployed using a guidewire), it does not suggest an endoscopic device (which does not use a guidewire because it is guided visually). Likewise, although the example of an angioplasty procedure may be suggestive of a stenting procedure (which is performed in combination with an angioplasty procedure), it does not suggest a tissue ligation procedure (which, unlike an artery-opening angioplasty procedure, ties off and closes tissue).

The combination suggested by the Office Action would require that the single limited example provided by *Zadno-Azizi* be suggestive of an entirely different type of medical device, for an entirely different medical procedure, within a different medical specialty. But this combination is one that could only be made through improper hindsight.

B. *Zadno-Azizi* Does Not Suggest Removing the Handle Actuation of *Yoon* and Replacing It With Applicant's Two-Way Actuator Made of a Composite Material

Independent claim 36 recites a "two-way actuator formed of composite material." The actuator has two different positions (a "first shape" and a "second shape") on account of the behavior of its component materials at different temperatures. As claimed, "at a temperature equal to or above A_f, said first shape memory alloy exerts a force against said second component which elastically deforms said second component so that said two-way actuator has said first shape," and "at a temperature equal to or below M_f, said force from said first shape memory alloy is at least partially released and a bias force of said second component acting on said first shape memory alloy returns the two-way actuator to said second shape." These shape changes cause the "finger portions" on the actuator to open and close "for grasping body tissue."

Yoon describes a ligation instrument having two grasping members 50A and 50B (see FIG. 1, for example), which can be closed by a surgeon squeezing a handle 40. These grasping members are initially in an open position, then moved to a closed position, and then returned back to the open position (see col. 7, lns. 47-50 and 65-67). From its initial open position, the grasping members are moved to the closed position when the user squeezes the handle 40 (see col. 9, lns. 7-14). This retracts the grasping members into tubular outer member 36, which pinches the grasping members together into the closed position (see col. 9, lns. 7-14). When the handle is released, a resilient bias causes the grasping members to return to their open position (see col. 9, lns. 32-35). Resilient bias towards the open position may result from the grasping members being made of a shape memory material (see col. 8, lns. 1-6), i.e., the material is shaped so that the grasping members are naturally biased towards the open position until acted upon by the handle. Thus, in *Yoon*, the shape memory material performs only one-way actuation (opening the grasping members), with the second-way actuation (closing the grasping members) being performed manually via a handle. In fact, this handle-type actuation is typical of prior art ligating devices like *Yoon*.

Zadno-Azizi does not provide any suggestion for replacing the handle-actuation of *Yoon* with Applicant's two-way actuation. In fact, with respect to the only medical device example disclosed by *Zadno-Azizi* (i.e., the guidewire) the reference explicitly states that the composite material is for a purpose that is wholly inapplicable to the *Yoon* device. *Zadno-Azizi* states that

the guidewire is designed to provide "good torque transmission and good pushability" (p. 15, lns. 11-13) or "anti-kinking capabilities" (p. 16, lns. 14-18). These features of "torque transmission," "pushability," and "anti-kinking properties" have no use in *Yoon*. Thus, a person of ordinary skill in the art would not be led to combine *Zadno-Azizi* with *Yoon*.

Moreover, even if *Zadno-Azizi* did disclose a proper teaching of two-way actuation, modifying *Yoon* to use a two-way shape memory actuator would interfere with its proper operation. As explained above, the *Yoon* ligator is designed to be operated manually by squeezing a handle. If the grasping members were to function as two-way actuators (both opening and closing), the handle would be rendered unnecessary. But there is no suggestion that the handles in the *Yoon* ligator be eliminated and replaced with grasping members that are two-way actuators. Indeed, the *Yoon* ligator relies on the handle for safe and proper operation. The handle allows grasping force exerted by the grasping members to "be controlled by controlling the extent to which the handle 40 is squeezed or compressed" (see col. 13, lns. 60-64). Further, the desired force can be "tactilely sensed by the surgeon through squeezing operation of the handle 40" (see col. 13, ln. 64 – col. 14, ln. 2).

Thus, manual control and tactile sensation transmitted through the handle are necessary for the surgeon to apply the desired amount of force to the grasping members. Replacing the handle with grasping members that function as two-way actuators would change the *Yoon* ligator's principle of operation.

Modifying *Yoon* in the manner suggested by the Office Action is improper because the proposed modification cannot change the principle of operation of a reference. *See* MPEP § 2143.01(VI). For at least these reasons, Applicant respectfully submits that claims 36-43 are patentable over *Zadno-Azizi* in view of *Yoon* and requests the allowance of these claims.

CONCLUSION

Applicant respectfully submits that the present application is now in condition for allowance. The Examiner is invited to contact Applicant's representative to discuss any issue that would expedite allowance of this application. Applicant petitions for a one-month extension of time and the Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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Steven S. Yu
Reg. No. 58,776

KENYON & KENYON LLP
1500 K Street, N.W., Suite 700
Washington, DC 20005
Tel: (202) 420-4200
Fax: (202) 420-4201